

### **REMARKS**

Claims 1-14 are currently pending in the application. Claims 1-14 have not been amended in response to the currently pending Office Action. Accordingly, no new matter has been added. Below is a response to the Examiner's rejection of claims 1-14 of the present application.

#### **Claim Rejection 35 U.S.C. § 102**

The Examiner rejected claims 1-8, 10, 13 and 14 under 35 U.S.C. § 102 as being anticipated by U.S. Patent No. 5,827,262 (Neftel). Applicants respectfully traverse this rejection.

Referring to Figs. 1-18b, Neftel discloses several embodiments of a syringe device for mixing two compounds. The syringe devices include a sleeve 14, 14''' for mounting between a syringe 12, 12' and a vial 10, 10' and two compounds, typically a fluid in the syringe 12, 12' and a powder in the vial 10, 10' are mixed by creating a fluid path between the syringe 12, 12' and the vial 10, 10'. Referring to Figs. 1-18b, in each of the embodiments of the syringe devices of Neftel, with the exception of the syringe device of the embodiments of Figs. 3, 4 and 13, a needle 34 is mounted directly to the syringe 12, 12' and does not detach from the syringe 34 before during or after being mounted to the sleeve 14, 14'''. In the embodiment of Figs. 3 and 4, the needle is replaced by a tubular piece 60, which is fixedly mounted within the sleeve 14 on radial fins 66 and is not mounted to the syringe 12 unless the syringe 12 is fully engaged with the sleeve 14. The tubular piece 60 is fixed in position relative to the sleeve 14 and only the syringe 12 moves relative to the sleeve 14 and vial 10 during operation in the embodiment of Figs. 3 and 4 of Neftel. Referring to the embodiment of Fig. 13, the syringe 12' includes a cylindrical adapter 246 fixedly mounted to its barrel, making the adapter 246 part of the syringe, because, without the adapter 246, fluid would flow out of the barrel. The cylindrical adapter 246 includes a frustoconical end 246b that releasably receives a head 248 of the needle 34' and the needle 34' includes ribs 254 extending therefrom. A portion or flange 260 extends inwardly from an inner surface of a guide piece 14a of the sleeve 14 and selectively engages the ribs 254 to prevent the needle 34' from being removed from the sleeve 14 when the syringe 12', including the fixedly mounted cylindrical adapter 246, is removed from the sleeve 14. Referring to the embodiment of Figs. 14a-14c, 18a and 18b, an annular seal 274 may be mounted in an upper part 204 of the

sleeve 14''' and is slidable relative to the sleeve 14'''. However, the annular seal 274 has a generally constant internal diameter with two inwardly extending lips 279, 281 that engage a barrel of the syringe 12 and the needle 34 mounted directly to the end of the syringe 12.

Referring to Figs. 1-4 and 9, the present application is directed to a syringe safety device 10 that is configured to form a fluid coupling between a sealed vial 12 and a syringe 24. The syringe safety device 10 includes a tubular connector 18 having opposing first and second open axial ends 18a, 18b and a sliding joint 22 that is received in the second open axial end 18b of the tubular connector 18. The first open axial end 18a of the tubular connector 18 is adapted to engage an end of the medicine vial 12 with a stopper 14 therein. The sliding joint 22 includes opposing first and second open axial ends 22a, 22b and a passageway extending between the first and second axial ends 22a, 22b. The first open axial end 22a of the sliding joint 22 is adapted to engage with an enlarged blunt mounting end 20b of a syringe needle 20. The second axial end 22b of the sliding joint 22 is adapted to releasably engage a releasable needle receiver 30 on a distal end of a barrel of the syringe 24 without a needle attached thereto. The syringe 24 is releasably removable from the sliding joint 22 after fluid coupling with the vial 12 through the passageway of the sliding joint 22 without removal of the sliding joint 22 from the tubular connector 18 and without removal of the needle 20 from the tubular connector 18.

Claim 1 is directed to a syringe safety device configured to form a fluid coupling between a sealed vial and a syringe and recites, as follows:

a tubular connector having opposing first and second open axial ends, the first open axial end being adapted to engage an end of a conventional medicine vial with stopper; and

a sliding joint received in the second open axial end of the tubular connector, the sliding joint having opposing first and second open axial ends and a passageway between the first and second open axial ends, the first open axial end being adapted to engage with an enlarged, blunt mounting end of a syringe needle, the second axial end of the sliding joint further being adapted to releasably engage at least a releasable needle receiver on a distal end of a barrel of a conventional syringe without needle, the syringe being releasably removable from the sliding joint after fluid coupling with the vial through the passageway of the sliding joint without removal of the sliding joint from the tubular connector and without the needle.

Applicants respectfully submit that none of the various embodiments of Neftel teach, suggest or disclose each and every element of currently pending claim 1 of the present application. Specifically, none of the embodiments of Neftel teach, suggest or disclose a sliding joint received in a tubular connector with a first open axial end adapted to engage a blunt mounting end of a syringe needle and an opposed second open axial end adapted to releasably engage a releasable needle receiver on a distal end of a barrel of a syringe. The only embodiment of the syringe device of Neftel that may be considered to include a sliding joint received in a tubular connector is the embodiment of Figs. 14a-14c, 18a and 18b wherein the sliding joint would be the annular seal 274. However, the annular seal of Neftel does not teach, suggest or disclose a first open axial end adapted to engage a blunt mounting end of a syringe needle and an opposed open axial end adapted to releasably engage a releasable needle receiver on a distal end of a barrel of a syringe, because the annular seal of Neftel merely engages an outer surface of the barrel of the syringe as opposed to a needle at one end and a needle receiver of a syringe on an opposed end, as is claimed in claim 1. In addition, none of the embodiments of Neftel, with the exception of the embodiments of Figs. 3, 4 and 13, permits release of the needle from the syringe such that the needle remains in the tubular connector or sleeve when the syringe is removed from the sliding joint after fluid coupling with the vial, as is claimed in claim 1, because the needle is fixed to the end of the syringe in these embodiments of Neftel.

Based upon the above, Applicants respectfully submit that none of the embodiments of the syringe device of Neftel teach, suggest or disclose each and every element of claim 1 and respectfully request that the Examiner reconsider and withdraw any rejection of claim 1 based upon anticipation by Neftel.

Claims 2-8, 10, and 13-14 are dependent on claim 1. Therefore, Applicants respectfully request that the Examiner reconsider and withdraw any rejection of claims 2-8, 10, and 13-14 based upon anticipation by Neftel due to their dependence upon claim 1 for the same reasons outlined above.

**Claim Rejections – 35 U.S.C. § 103**

The Examiner rejected claims 9, 11 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Neftel. The Examiner argues that Neftel discloses each and every element of

claims 9, 11 and 12 except for providing sealed sterile packaging. The Examiner asserts that it would have been obvious to one skilled in the art to package the components together in sealed sterile packaging. Applicants respectfully traverse this rejection.

Claims 9, 11 and 12 are dependent upon claim 1. As was described above, Applicants respectfully submit that Neftel does not teach, suggest or disclose each and every element of currently pending claim 1. Further, Applicants respectfully submit that even if Neftel was modified to include the sterile packaging, as was proposed by the Examiner, the modified device would not include each and every element of claim 1, wherein the deficiencies of Neftel were outlined in detail above. In addition, Applicants respectfully submit that one having ordinary skill in the art would not modify Neftel to include the above-described elements and there is no motivation in Neftel or in the knowledge of one having ordinary skill in the art to modify Neftel to include the above-listed elements or the sterile packaging claimed in claims 9, 11 and 12, as was proposed by the Examiner.

Based upon the above arguments, Applicants respectfully request that the Examiner reconsider and withdraw any rejection of claims 9, 11 and 12.

**CONCLUSION**

In view of the foregoing Request for Reconsideration and remarks, Applicants respectfully submit that the present application, including claims 1-14, is in condition for allowance and such action is respectfully requested.

Respectfully submitted,

**PHILLIP A. GRAY**

February 9, 2007 By: Dennis J. Butler  
(Date) **DENNIS J. BUTLER**  
Registration No. 51,519  
**AKIN GUMP STRAUSS HAUER & FELD LLP**  
One Commerce Square  
2005 Market Street, Suite 2200  
Philadelphia, PA 19103-7013  
Telephone: 215-965-1200  
**Direct Dial: 215-965-1292**  
Facsimile: 215-965-1210  
E-Mail: dbutler@akingump.com

DJB/JLH